REMARKS

Claims 1-11 and 21-32 are pending. Claims 12-15 have been withdrawn by the Examiner, and claims 23-32 are new.

Claims 1, 3-5, 7, 9, 11 and 21-22 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over EP 0 405 284 A2 to Greiner, in view of U.S. Patent No. 6,087,003 to Benoit et al. Claims 2-3, 8-10 and 22 also stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Greiner in view of Benoit as applied to claims 1, 3-5, 7, 9, 11, and 21-22, and further in view of U.S. Patent No. 6,555,157 to Hossainy.

ELECTION/RESTRICTIONS

Claims 12-15 were *sua sponte* withdrawn by the Examiner in the last Office Action allegedly pursuant to 37 CFR § 1.142(b) and MPEP § 821.03. Reconsideration of this withdrawal is requested as claim 12 was simply amended in the last response to include language from claim 15, a dependent claim that, like claim 12, has been pending since the case was originally filed more than three years ago. Consequently, the assertions in the Office Action that previously pending claim 12 did not require a separate swelling step is misleading because, while claim 12 may not have included that particular step, claims that depended from claim 12 did. Thus, restriction of this subject matter from the case at this point in time, three years after the prosecution has begun, three years after the subject matter was originally presented for examination, and many years after the material was first examined, is inappropriate.

The discussion in the Office Action directed to the originally presented species of claim 8 is also misplaced as the subject matter has also been pending for more than three years.

Consequently, reconsideration and retraction of the restriction requirement is requested.

35 U.S.C. § 112

The Office Action recognizes that any alleged § 112 issues have been resolved in the case.

35 U.S.C. § 103

Claim 1 stands rejected as allegedly being obvious in light of Greiner, in view of Benoit.

Greiner is entitled "Pharmaceutically Impregnated Catheters" and relates to "a catheterization system which incorporates impregnating a pharmaceutical into a catheter by contacting the catheter with a volatile solvent or swelling agent." (Emphasis added) This system in Greiner includes immersing a catheter in the liquid solution containing a pharmaceutical and then exposing the catheter to conditions that are at or near the supercritical conditions for a swelling agent containing the pharmaceutical in order to permit "rapid impregnation of the mixture into the catheter."

Benoit, entitled "Method of Coating Particles and Coated Spherical Particles," regards a method for "entrapping . . . active substances in a coating material which is conformationally distributed on said active substance and has a thickness ranging from the thickness of a monomolecular layer to about 100 μm." In practicing the process of Benoit an active substance and a coating material may be placed in an autoclave which is then filled with a supercritical fluid. Thus, the active substance is not carried by the supercritical fluid, but is, rather, prepositioned in the autoclave prior to the introduction of the SCF.

The Office Action asserts "it would have been obvious to one of ordinary skill in the art to use the teachings of Benoit in a method of Greiner to provide Greiner with an apparatus capable of handling the supercritical coating operation of Greiner that would be effective and safe for medical and active substances." This argument fails for several reasons. For one, both Greiner and Benoit fail to disclose or suggest transporting a therapeutic in an SCF. In both Greiner and Benoit the active material is in a chamber with the object to be treated, it is not carried by an SCF as recited in the claim. For another, there is no reason to believe that one of skill in the art would even modify these references to meet the recited language as supplying additional therapeutic via an SCF would be redundant as the material is already near the target material when the SCF is introduced.

As to claim 2, the undersigned submits that neither Greiner nor Benoit at least describes or suggests applying the carrier coating to a medical device. In Greiner the therapeutic is impregnated into the catheter, thus it is not intended to act as a carrier coating to carry therapeutic on a device. In addition, in Benoit, the coating that is sprayed on the small microparticles is a barrier coating overlaying the microparticles. It is not a carrier coating as recited in the claim.

As to claim 3, none of the three patents used to reject this claim suggest or describe

spraying the supercritical fluid at the medical device. While Hossainy may mention the word spray in column 2, line 44, and column 3, line 39, nowhere in Hossainy is a supercritical fluid sprayed. Thus, it cannot be a basis for rejecting claim 3.

As to claim 6, the undersigned submits that since Hossainy does not describe or suggest the use of supercritical fluids, it is impossible for it to render claim 6 unpatentable as claim 6 recites "the therapeutic is colloidally suspended in the supercritical fluid." The discussion in the Office Action that Hossainy "appears to meet the limitation of claim 6," does not address the simple fact that Hossainy does not regard supercritical fluids in any way.

As to claim 8, the undersigned submits that none of the cited references disclose or suggest interfacing a therapeutic combined with a carrier coating as in the claim. Since Hossainy does not address supercritical fluids, it is impossible for it to disclose or suggest this claim language. As to Benoit, only a single coating material is in the supercritical fluid so it, too, does not disclose or suggest a carrier and therapeutic in supercrital fluid as recited.

As to claim 9, none of the references at least disclose or suggest "removing residual therapeutic from the supercritical fluid." While the Office action argues that Hossainy discloses this language, the undersigned submits that this statement is erroneous. As noted above, Hossainy does not disclose or suggest the use of supercritical fluid so the recited claim language, which regards removing residual therapeutic from supercritical fluid, cannot and is not disclosed.

As to claim 22, similar logic applies. For one, supercritical fluid is not collected in Hossainy so it cannot disclose or suggest this language. Moreover, residual therapeutic is not removed from any solvent in Hossainy so for this reason as well claim 22 is patentable over it. Still further, Hossainy does not suggest or disclose the step of reusing residual therapeutic by interfacing the residual therapeutic with the supercritical fluid as recited in claim 22. For at least each of these reasons, claim 22 is patentable over Hossainy and all of the other cited references.

NEW CLAIMS

Several new claims have been added. Each of these claims has support in the as-filed specification. For instance, claims 24-27 find support in as-filed claim 11 and claims 29 and 30 find support in Figs. 2-4 and its supporting specification. As to claim 24, the subject matter of which has been addressed in previous Office actions and responses, the undersigned submits that

it does not constitute new matter at least because medical devices are recited in the preamble and throughout the specification and because stents, which are metallic, are medical devices.

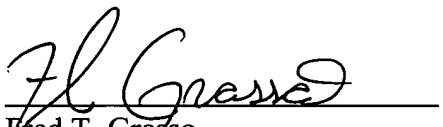
CONCLUSION

The claims are patentable over the cited references for at least the proceeding reasons. Reconsideration in light of the proceeding remarks is requested.

Should the Examiner have any questions regarding this submission, she is invited to contact the undersigned at 202-220-4311.

Respectfully submitted,

Dated: August 31, 2004



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